#17 Appeal Brief T. Lauf 12-24-02

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Krivitski, Nikolai M.	Atty. Docket:	86017.000010
Serial No.:	09/419,849	Examiner:	Charlene Dickens
Filed:	October 19, 1999	Art Unit:	2855
Title:	METHOD AND APPARATUS TO MEASURE BLOOD FLOW BY AN INTRODUCED VOLUME CHANGE		

APPELLANT'S BRIEF

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

1. Real Party and Interest

The real party and interest is Transonic Systems, Inc., 34 Dutch Mill Road, Ithaca, New York 14850.

2. Related Appeals and Interferences

There are no other appeals or interferences known to appellant, the appellant's legal representative, or assignee which will affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. Status of Claims

All the pending claims in the application, Claims 1-38, stand rejected and is subject to the present appeal.

4. Status of Amendments

An Amendment After Final Rejection was filed July 17, 2002. In the Advisory Action (Paper 15) mailed August 13, 2002, the examiner advised applicant that the Amendment After Final would be entered upon filing an appeal.

5. Summary of Invention

The present invention is directed to a method for determining an initial flow rate of liquid in a conduit (Figure 1, Reference 10; Page 7, Lines 9-19), comprising:

(a) introducing a discrete known volume over a known time to the initial flow rate (Q_i in Figure 1; Page 9, Lines 5-6; Page 13, Equation 5);

(b) sensing a corresponding resulting change in the flow in the conduit (Page 9, Lines 9-19; Lines 20-24; Page 13, Lines 7-17) and;

(c) determining the initial flow rate in response to the introduced known volume, the known time and the sensed resulting change. (Page 3, Lines 3-4; Page 3, Lines 20-23; Page 9, Lines 20-24; Page 10, Lines 1-8; Page 13, Lines 7-17)

6. Issues

1. Whether Claims 1-38 are properly rejected under 35 U.S.C. §102(b) as being anticipated by Krivitski, *et al.* (U.S. Patent No. 5,685,989).

7. Grouping of Claims

Claims 1-10 stand or fall together.

Claims 11-19 stand or fall together.

Claims 20-21 stand or fall together.

Claims 22-24 stand or fall together.

Claim 25 stands or falls alone.

Claims 26-36 stand or fall together.

Claim 37 stands or falls alone.

Claim 38 stands or falls alone.

8. Argument

(i) Rejections Under 35 U.S.C. §112, First Paragraph

There are no outstanding rejections under 35 U.S.C. §112, first paragraph.

(ii) Rejections Under 35 U.S.C. §112, Second Paragraph

There are no outstanding rejections under 35 U.S.C. §112, second paragraph.

(iii) Rejections Under 35 U.S.C. §102

All the pending claims, Claims 1-38, stand rejected under 35 U.S.C. §102(b) as being anticipated by Krivitski U.S. Patent No. 5,685,989 (the '989 patent).

Examiner Dickens asserts the '989 patent discloses "a volume change" as claimed. The examiner states that "the term 'volume change' in the claims is used by the claim to mean 'a known volume over a known time,' while the accepted meaning is a 'change in capacity in a region'." [Paper 13, Page 3] The examiner thus concludes that the limitation "a known volume over a known time" is not recited in the rejected claims. [Paper 13, Page 3]

"The examiner believes Krivitski '989 does teach a "volume change" as claimed. In response to applicant's argument that the reference fails to show certain features of the applicant's invention, it is noted that the features upon which applicant relies (i.e., a known volume over a known time) are not recited in the rejected claim(s)." [Paper 13, Page 3]

THE TERM 'VOLUME CHANGE' DOES NOT APPEAR IN 16 OF THE CLAIMS.

As a preliminary matter, applicant directs the Board's attention to the following portions of certain pending claims:

"Introducing a discrete known volume over a known time" (Claims 1-10);

"Introducing a discrete known volume over a known time" (Claims 20-21);

"Means for introducing a discrete known volume over a known time" (Claims 22-25)

Applicant's have not properly amended claim in accordance w/ 37 CFR 1.121(c)

Examiner Dickens has not provided a basis for the rejection of these claims, which recite "a known volume over a known time", and yet have been deemed by the examiner to not recite "a known volume over a known time." [Paper 13, Page 3]

That is, Examiner Dickens has read these limitations to recite a 'volume change'. As the Examiner has asserted the '989 patent discloses a volume change (which the examiner states is not a known volume over a known time), these claims which recite a known volume over a known time are <u>not</u> properly rejected.

These claims (1-10, 20-25) do <u>not</u> recite a 'volume change' but rather 'introducing a discrete known volume over a known time." The Examiner has defined a 'volume change' to be a 'change in capacity in a region'. [Paper 13, Page 3] In accordance with the Examiner's interpretation, there is no "known time" parameters in the '989 patent. Therefore, the limitation of 'introducing a known volume over a known time" is not present in the '989 patent. The absence of at least this limitation precludes the '989 patent from sustaining the asserted rejection of these 16 claims.

"Volume Change"

Examiner Dickens recognizes that applicant may be his or her own lexicographer, yet the examiner asserts accepted meaning that for the term "volume change" "the accepted meaning is a "change in capacity in a region" [Paper 13, Page 3] However, the

examiner has provided no basis for this "accepted meaning." That is, no dictionary or treatises have been cited.

Examiner Dickens has ignored the express teachings of the specification. Specifically:

> All of these introduce a metered change "known flow rate" to the flow to be measured in the conduit. This metered change in flow, independent of how the change is induced, constitutes the "volume change." *The volume change is a known volume over a known time.* That is, a known, measured or measurable change is introduced to the initial flow whose flow rate is to be determined. [emphasis added] [Page 9, Lines 5-8]

Further, as set forth in the specification, Q designates a volumetric flow rate which is a measure of the volume of liquid passing a cross sectional area of the conduit per unit time and maybe expressed in units such as milliliters per minute (ml/min) or (l/min) [Page 7, Lines 9-16; and Page 12, Lines 4-5; Page 13, Lines 8-11]

Examiner Dickens has ignored this clear and deliberate definition. To support her assertion that use of the term "volume change" to mean "a known volume over a known time" is a repugnant to the usual meaning of the term "volume change", the examiner cites *In re Hill, 73 USPQ 482 (CCPA 1947)*.

In *Hill*, the examiner objected to the term "carbamide formaldehyde resin including the resins made from formaldehyde and urea, thiourea, melamine, and other urea derivatives and substituted ureas" for inclusion of the term "carbamide". The Examiner found the meaning of the term "carbamide" to be objectionable on the basis of:

> (1) Webster's New International Dictionary which defines carbamide as being synonymous with the term "urea";
>
> (2) Melamine is not urea;
>
> (3) No examples were set forth in the specification to make clear the meaning of "urea derivatives" and "substituted ureas";
>
> (4) The scope of the term "derivative" is dubious;
>
> (5) Certain "substituted ureas" such as tri-ethyl urea and tetra ethyl urea do not form resins with formaldehyde.

Based upon these reasons, the asserted definition from the specification was held to be objectionable as placing a distorted meaning on the "carbamide" (*In re Hill,* at 483)

In the present application, the examiner has:

(1) not cited any dictionary or even more preferred standard textbook definitions which renders the objected term internally inconsistent;

(2) not identified any lack of examples in the specification; and

(3) not identified any included unworkable examples.

In contrast to *Hill*, the present use of volume change is:

(1) internally consistent;

(2) and clearly set forth in the written description.

> All of these introduce a metered change "known flow rate" to the flow to be measured in the conduit. This metered change in flow, independent of how the change is induced, constitutes the "volume change." *The volume change is a known volume over a known time.* That is, a known, measured or measurable change is introduced to the initial flow whose flow rate is to be determined. [emphasis added] [Page 9, Lines 5-8]

The Board's attention is directed to Page 2, Line 22 - Page 3, Line 1, which recite:

> The present family of volume change methods to measure an initial flow rate implement the following steps:
>
> Introducing (i.e., injecting or withdrawing) a known volume of fluid over a know time (or measured time), that is introducing a known flow rate to the initial flow such that the "introduced volume change" will produce one or more "resulting changes" in the flow to be measured;"

As stated by the Court of Appeals for the Federal Circuit in *Markman v. Westview Instruments, 34 USPQ2d 1321, 1329-1330 (Fed. Cir. 1995) affirmed 38 USPQ2d 1461 (U.S. 1996)*:

> Claims must be read in view of the specification, of which they are a part. *Autogiro*, 384 F.2d at 397, 155 USPQ at 702; see *Winans v. Denmead*, 56 U.S. (15 How.) at 338; Bates v. Coe, 98 U.S. at 38-39. The specification

> contains a written description of the invention that must enable one of ordinary skill in the art to make and use the invention. For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. See *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 621 (CCPA 1970) ("Occasionally the disclosure will serve as a dictionary for terms appearing in the claims, and in such instances the disclosure may be used in interpreting the coverage of the claim."). As we have often stated, a patentee is free to be his own lexicographer. *Autogiro*, 384 F.2d at 397, 155 USPQ at 702. The caveat is that any special definition given to a word must be clearly defined in the specification. *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992).
>
> Where an inventor chooses to be his own lexicographer and to give terms uncommon meanings, he must set out his uncommon definition in some manner within the patent disclosure. See *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 889, 221 USPQ 1025, 1031 (Fed. Cir. 1984). In Lear we stated that: So long as the meaning of an expression is made reasonably clear and its use is consistent within a patent disclosure, an inventor is permitted to define the terms of his claims. Nevertheless, the place to do so is in the specification of the inventor's application, and the time to do so is prior to that application acquiring its own independent life as a technical disclosure through its issuance as a United States patent. *Intellicall Inc. v. Phonometrics Inc.* (Fed. Cir.) 21 USPQ2d 1383
>
> Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision. "Where an inventor chooses to be his own lexicographer and to give terms uncommon meanings, he must set out his uncommon definition in some manner within the patent disclosure" so as to give one of ordinary skill in the art notice of the change. See *Intellicall, Inc., v. Phonometrics, Inc.*, 952 F.2d 1384, 1387-88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)." In re Paulsen (Fed. Cir.) 31 USPQ2d 1671

Examiner Dickens has made no showing that the term "volume change" as set forth in the claims and defined the specification so lacks any reasonable clarity, deliberateness and precision that one of ordinary skill in the art would not understand the recited definition of volume change as set forth in the written description.

Further, Examiner Dickens relies upon *In re Van Geuns, 26 USPQ 2d 1057 (Fed. Cir. 1993)* for the proposition that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. However, *In re Van Geuns*, is directed to an interference proceeding, where the count identically

corresponded to applicant's claim. The claim was silent as to the field of use with which the magnetic assembly is employed and did not recite any specific uniformity of a magnetic field, nor was the specification cited to provide any quantitative level of uniformity. Thus, the Federal Circuit stated that reference in the specification to NMR imaging would not be read into the claim to limit the claim to NMR and MRI technology, wherein the term "uniform" would be understood by those of skill in the art in NMR and MRI art to require better than 10 percent variance from uniformity.

Van Geuns is inapplicable to the present appeal. The present claims are not silent as to the limitations at issue, but rather rely upon a definition clearly set forth in the specification.

Further, Examiner Dickens has not accounted for the Federal Circuit decision *In re Morris,*

> Since it would be unreasonable for the PTO to ignore any interpretive guidance afforded by the applicant's written description, either phrasing connotes the same notion: as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, *taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.*" [emphasis added] *In re Morris* 44 USPQ2d 1023, (Fed. Cir. 1997)

Applicant respectfully submits the term volume change is not so repugnant that it cannot have the meaning asserted by applicant. That is, the term volume is defined as an amount of three-dimensional space occupied by an object. Worldnet Princeton University, Copyright 1997. [Worldnet 1.6 Copyright 1997, Princeton University]. The term change is "an event that occurs when something passes from one state or phase to another" or "to cause to change, make different". Worldnet Copyright 1997 Princeton University. Thus, "to create a discrete volume change in the initial flow" (with no reference to the specification whatsoever) would clearly suggest a change in the volume of the flow defined for a finite or countable set of values, such as time.

Claims 1-10

In a method for determining an initial flow rate of liquid in a conduit, independent Claim 1 recites in part "introducing a discrete known volume over a known time to the initial flow rate."

Examiner Dickens has not identified any portion of the '989 patent that discloses "introducing a known volume over a known time." This limitation is absent from the cited reference. Therefore, the asserted rejection cannot be sustained.

Examiner Dickens construed the '989 patent to disclose a volume change. However, as Claim 1 does not recite a "volume change" but rather a "discrete known volume over a known time," this limitation is not met.

Further, the examiner has made the following assertions:

(i) Krivitski '989 discloses a "volume change";

(ii) The term "volume change" is deemed to mean "a change in capacity in a region";

(iii) "The features upon which applicant relies (i.e., a known volume over a known time) are not recited in the rejected claim(s)." [Paper 13, Page 3]

Yet, Claim 1 does not recite a "volume change" and recites "a discrete known volume over a known time."

Therefore, as Claim 1 recites "introducing a discrete known volume over a known time" and by the examiner's construction, this limitation is absent from the '989 patent, the asserted rejection cannot be sustained.

As Claims 2-10 depend from Claim 1 and include all limitations thereof, these claims are also in condition for allowance.

Claims 11-19

Claim 11 recites in part, "introducing a known flow rate to the initial flow rate through the catheter."

Examiner Dickens does not identify any portion of the '989 patent which discloses "introducing a known flow rate to the initial flow rate." A flow rate is a measure of the volume of liquid passing across sectional area of a conduit *per unit time* and is expressed in units of volume per time. [emphasis added] (Page 7, Lines 9-18) As the examiner has not identified introducing a known flow *rate* to the initial flow, this limitation is absent.

Further, Claim 11 recites in part, "determining the initial flow rate in response to the introduced known flow rate..."

As Examiner Dickens has not identified introducing a known flow rate to the initial flow rate, the '989 patent cannot disclose "determining the initial flow rate in response to the introduced known flow rate ..."

Independent Claim 11 recites in part, "locating a catheter in the conduit." Examiner Dickens relies upon elements 26 and 32 of Krivitski '989 to disclose a catheter. [Paper 13, Page 2]

As set forth in the '989 patent, an arterial line, or tube 26 having an inlet 28 in the shunt for drawing blood for treatment by the dialysis equipment . . . a venus line, or tube, 32 which carries treated blood from the dialysis equipment 24 back to the shunt. The venus line 32 has an outlet 34 located in shunt 12, upstream of the arterial line inlet 28." (Col. 5, Lines 36-42)

In contrast, a catheter is defined as "a hollow flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway."[1]

[1] The American Heritage Dictionary of the English Language, Fourth Edition, Copyright 2000 by Houghton-Mifflin Company.

Examiner Dickens provided no basis for the asserted equivalence of the arterial and venus line in the '989 patent to be catheters.

The absence of at least these limitations precludes the '989 patent from sustaining the asserted rejection of Claim 11.

As Claims 12-19 depend from Claim 11 and include all limitations thereof, these claims are also in condition for allowance.

Claims 20-21

Independent Claim 20 recites in part, "introducing a discrete known volume over a known time . . ."

Examiner Dickens has asserted:

(i) The '989 references discloses a "volume change" which is "a change in capacity in a region." [Paper 13, Page 3]

(ii) "It is noted that the features upon which applicant relies (i.e., a known volume over a known time) are not recited in the rejected claim(s). [Paper 13, Page 3]

As independent Claim 20 recites "introducing a discrete known volume over a known time" The asserted rejection cannot be sustained.

Claim 20 further recites in part, "determining the initial flow rate in response to the introduced discrete known volume, the known time ..."

As the '989 patent does not disclose introducing a discrete known volume over a known time, there can be no determining the initial flow rate in response to the introduced discrete known volume and the known time. Thus, this limitation is also absent. The absence of at least these limitations precludes the '989 patent from sustaining the asserted rejection. As Claim 21 depends from Claim 20 and includes all the limitations thereof, the asserted rejection of this claim is not sustainable.

Claims 22-24

Claims 22-24 recite in part, "means for introducing a discrete known volume over a known time to the initial flow."

The outstanding rejection is based upon the examiner's assertion that:

(i) The '989 patent discloses "a change in capacity in a region." [Paper 13, Page 3];

(ii) "It is noted that the features upon which applicant relies (i.e., a known volume over a known time) are not recited in the rejected claim(s)." [Paper 13, Page 3]

As Claims 22-24 recite in part "means for introducing a discrete known volume over a known time" and this limitation is not present in the '989 patent, the asserted rejection cannot be sustained.

Further, Claims 22-24 recites in part, "a controller ... configured to determine the initial flow rate in response to the known volume, the known time."

As the '989 patent does not introduce a known volume over a known time, there is no controller configured to determine the initial flow rate in response to the known volume and the known time. Therefore, this limitation is also absent.

The absence of at least these limitations requires the asserted rejection of Claims 22-24 be reversed.

Claim 25

Independent Claim 25 recites in part, "a known *flow rate* introducer." [emphasis added]

Flow rate is defined as a known volume over a known time, and as the '989 patent has been construed to disclose only "a change in capacity in a region", this limitation is absent from the '989 patent.

Claim 25 further recites, "a controller...configured to determine the initial flow rate in response to the known flow rate." As the '989 patent does not disclose the known flow rate introducer, there is no controller configured to determine the initial flow rate in response to the known flow rate, therefore this limitation is also absent.

Claims 26-36

Claims 26-36 recite in part, "introducing a *known flow rate* of an indicator into a conduit to create a discrete volume change in the initial flow." [emphasis added]

As previously set forth, flow rate is defined in terms of a volume per unit time and Examiner Dickens has not identified any such corresponding disclosure in the '989 patent.

Further, the creation of "a discrete volume change in the initial flow" resulting from a known flow rate is not shown in the '989 patent. Specifically, a volume change in a known volume over a known time. (Page 9, Line 7)

Claims 26-36 further recite in part, "determining the initial blood flow rate in the conduit in response to the introduced known flow rate indicator."

As Examiner Dickens has not identified any corresponding introduction of a known flow rate in the '989 patent, there is no determining the initial flow rate in response to the introduced known flow rate.

Further, Examiner Dickens cites Col. 5, Line 64 - Col. 6, Line 67 of the '989 patent [Paper 13, Page 2] to disclose determining the initial flow rate in response to the introduced volume change and the sensed resulting change. This portion of the '989 patent states:

> **shunt blood flow determination. This improved accuracy is obtained in accordance with Equations 2 and 3. Although**

$$Q_{shunt}+Q_{dial}=V_{ven}/S_{art} \quad \text{(Eq2)}$$

$$Q_{shunt}=V_{ven}/S_{art}-Q_{dial} \quad \text{(Eq. 3)}$$

That is, the examiner relies upon determining the blood flow through the shunt Q_{shunt} in terms of a volume of indicator and an absolute *concentration* of the indicator in the arterial line S_{art}. The examiner has not shown a determination of a flow rate in the shunt in response to an introduced flow rate. That is, the defining time component is not identified by Examiner Dickens.

Therefore, the rejection of Claims 26-36 cannot be sustained.

Claim 37

Independent Claim 37 recites in part, "determining an initial blood flow rate Q corresponding to five relationships. Each relationship sets forth a dependence of Q to Q_i, where Q_i is the introduced volume during the introduced time. Q_i is a flow rate. That is, a volume over a given time. Again, Examiner Dickens has not identified any portion of the '989 patent which sets forth a known introduced volume over a time.

Claim 38

Independent Claim 38 recites in part, "determining the initial flow rate Q, corresponding to an introduced flow rate to the initial flow rate."

The introduced flow rate is defined as a given volume over a given time. The introduction of a given volume, without the recited parameter of the given time, as set forth in the '989 patent, cannot sustain the asserted rejection.

(iv) Rejections Under 35 U.S.C. §103

There are no outstanding rejections under 35 U.S.C. §103.

(v) There are no other outstanding grounds of rejection not covered by Paragraphs (i) - (iv)

CONCLUSION

At least the following factors require that the outstanding rejection of Claims 1-38 under 35 U.S.C. §102(b) be reversed:

(1) The introduction of a known volume over a known time is clearly recited in the claims;

(2) The term "a volume change" is sufficiently set forth in the written description to sustain that applicant's asserted meaning;

(3) The lack of introducing a known volume over a known time in the '989 patent.

Respectfully submitted,

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Appendix

1. (Once Amended) A method for determining an initial flow rate of a liquid in a conduit, comprising:

(a) introducing a discrete known volume over a known time to the initial flow rate;

(b) sensing a corresponding resulting change in the flow in the conduit; and

(c) determining the initial flow rate in response to the introduced known volume, the known time and the sensed resulting change.

2. (Once Amended) The method of Claim 1, wherein introducing the discrete known volume over the known time includes injecting or withdrawing the discrete volume from the conduit.

3. The method of Claim 1, further comprising employing one of a flow characteristic sensor and a liquid characteristic sensor.

4. (Once Amended) The method of Claim 1, wherein sensing the corresponding resulting change includes sensing at an upstream location to the introduced volume and a downstream location to the introduced volume.

5. The method of Claim 1, wherein sensing the corresponding resulting change includes employing a sensor located at one of in the conduit, on the conduit or spaced from an exterior of the conduit.

6. (Once Amended) The method of Claim 1, wherein introducing the discrete known volume over a known time includes introducing the discrete known volume over a known time through a catheter in the conduit.

7. The method of Claim 1, further comprising sensing the corresponding resulting change in one of a liquid characteristic and a flow characteristic.

8. The method of Claim 1, wherein sensing a corresponding resulting change includes sensing a corresponding resulting change proportional to the flow in the conduit.

9. The method of Claim 1, wherein sensing a corresponding resulting change includes sensing one of a velocity, pressure and flow rate of the flow in the conduit.

10. The method of Claim 1, wherein sensing a corresponding resulting change includes sensing a dilution indicator.

11. (Once Amended) A method for determining an initial flow rate in a conduit, comprising:

(a) locating a catheter in the conduit;

(b) introducing a known flow rate to the initial flow rate through the catheter; and

(c) determining the initial flow rate in response to the introduced known flow rate and a resulting change in the initial flow rate.

12. (Once Amended) The method of Claim 11, wherein introducing a known flow rate includes introducing a discrete volume change.

13. (Once Amended) The method of Claim 11, wherein introducing a known flow rate includes injecting or withdrawing a discrete volume from the conduit.

14. The method of Claim 11, further comprising employing one of a flow characteristic sensor and a liquid characteristic sensor.

15. (Once Amended) The method of Claim 11, wherein sensing the corresponding resulting change includes sensing at an upstream location to the introduced known flow rate and a downstream location to the introduced known flow rate.

16. The method of Claim 11, wherein sensing a corresponding resulting change includes sensing with a sensor located at one of in the conduit, on the conduit or spaced from an exterior of the conduit.

17. (Once Amended) The method of Claim 11, further comprising sensing a resulting change after introducing the known flow rate.

18. (Once Amended) The method of Claim 17, wherein sensing the resulting change includes sensing a change corresponding to the introduced known flow rate in one of a liquid characteristic and a flow characteristic.

19. The method of Claim 17, further comprising sensing a resulting change as proportional to the flow in the conduit.

20. (Once Amended) A method for determining an initial flow rate in a conduit, comprising:

(a) introducing a discrete known volume over a known time to the initial flow in the conduit to produce a resulting change in the initial flow; and

(b) determining the initial flow rate in response to the introduced discrete known volume, the known time and the resulting change.

21. The method of Claim 20, further comprising employing a sensor to sense the resulting change in the flow.

22. (Once Amended) An apparatus for determining an initial flow rate in a conduit, comprising:

(a) means for introducing a discrete known volume over a known time to the initial flow;

(b) a sensor for measuring a corresponding change resulting from the introduced discrete known volume over the known time; and

(c) a controller connected to the sensor, the controller configured to determine the initial flow rate in a response to the known volume, the known time and the corresponding change.

23. The apparatus of Claim 22, further comprising a catheter having an introduction port.

24. The apparatus of Claim 23, wherein the sensor is connected to the catheter.

25. (Once Amended) An apparatus for determining an initial flow rate in a conduit, comprising:

(a) a known flow rate introducer selected to effect a discrete known flow rate to produce a resulting change in the initial flow in the conduit;

(b) a sensor for measuring the resulting change; and

(c) a controller connected to the sensor, the controller configured to determine the initial flow rate in a response to the known flow rate and the resulting change measured by the sensor.

26. (Once Amended) A method for determining an initial blood flow rate in a conduit, comprising:

(a) introducing a known flow rate of an indicator into the conduit to create a discrete volume change in the initial flow and a liquid characteristic change in the conduit;

(b) optically sensing the liquid characteristic change in the conduit with a sensor located external to the conduit; and

(c) determining the initial blood flow rate in the conduit in response to the introduced known flow rate of indicator and the sensed liquid characteristic change.

27. (Once Amended) The method of Claim 26, wherein introducing the known flow rate of the indicator includes introducing a change in blood hematocrit in the conduit.

28. (Once Amended) The method of Claim 26, wherein introducing the known flow rate of the indicator includes introducing a solution including at least one of saline and glucose into the conduit.

29. The method of Claim 28 further comprising introducing an isotonic solution into the conduit.

30. The method of Claim 26, wherein optically sensing the liquid characteristic change includes obtaining a value proportional to the liquid characteristic change.

31. (Once Amended) The method of Claim 26, wherein introducing the volume of the indicator into the conduit includes introducing the known flow rate of indicator upstream of an area sensed by the optical sensor.

32. The method of Claim 26, wherein the liquid characteristic is blood hematocrit.

33. The method of Claim 26, wherein optically sensing the liquid characteristic change includes obtaining a value proportional to blood hematocrit in the conduit.

34. (New) The method of Claim 1, further comprising measuring to identify one of the known volume and the known time.

35. (New) The method of Claim 11, further comprising determining the known flow rate by measuring.

36. (New) The method of Claim 20, wherein one of the known volume and the known time is determined by measuring.

37. (New) A method for determining an initial blood flow rate in a conduit, comprising:

(a) determining the initial blood flow rate Q, corresponding to at least one of the following and an analogous relationships:

$$Q = \frac{Q_i}{\left(\frac{\Delta Q_d}{Q_d} - \frac{\Delta Q_u}{Q_u}\right)}; \quad Q = \frac{Q_i}{(C_{bd} - C_{bu})}; \quad Q = \frac{Q_i}{\left(\frac{\Delta V_d}{V_d} - \frac{\Delta V_u}{V_u}\right)};$$

$$Q = \frac{Q_i}{\left(\frac{\Delta hu}{hui} - \frac{\Delta hd}{hdi}\right)}; \quad Q = \frac{Qi}{\left(\frac{\Delta Pd}{Pd - Pven} - \frac{\Delta Pu}{Pu - Part}\right)}$$

where Q_i is the introduced volume during the introduced time;

$\Delta Q_d = Q_{di} - Q_d$;

$\Delta Q_u = Q_{ui} - Q_u$;

Q_d is the flow rate downstream of an introduction point of Q_i;

Q_u is the flow rate upstream of an introduction point of Q_i;

C_{bd} is the relative change in a flow corresponding parameter from an upstream volume injection;

C_{bu} is the relative change in a flow corresponding parameter from a downstream volume injection;

ΔV_u is a change corresponding to an upstream blood velocity;

ΔV_d is a change corresponding to a downstream blood velocity;

V_u is an upstream blood velocity;

V_d is a downstream blood velocity;

hu is a concentration of indicator measured at an upstream sensor;

hd is a concentration of indicator measured at a downstream sensor;

Δhu = hui-hu; and

Δhd = hdi-hd.

38. (New) A method for determining an initial blood flow rate in a conduit, comprising:

(a) determining the initial blood flow rate Q, corresponding to an introduced flow rate to the initial flow rate.